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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,309	02/11/2004	Dilip Tapadiya	TAPADI.003C1	3507
20995	7590	06/30/2006	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			KIDWELL, MICHELE M	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3761	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/776,309	<b>Applicant(s)</b> TAPADIYA, DILIP	
	<b>Examiner</b> Michele Kidwell	<b>Art Unit</b> 3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-50 and 99-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-50 and 99-103 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/11/04;01/04/06</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS filed 05/05/06</u> .               |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 101 is objected to because of the following informalities: the claim recites that the has an umbrella shape. The claim is unclear. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 99 – 101 are rejected under 35 U.S.C. 102(b) as being anticipated by Gottesman (4,834,068).

With reference to claim 99, Gottesman et al. (hereinafter "Gottesman") discloses an irrigation shield comprising a flexible sheet having an elastically enlargeable aperture configured to releasably engage a head of an irrigation nozzle as set forth in col. 4, lines 4 – 17.

As to claim 100, Gottesman discloses an irrigation shield further comprising a latex portion circumferentially attached to the aperture, the latex portion having an elastically enlargeable opening for receiving the irrigation nozzle as set forth in col. 4, lines 6 – 11 and in figure 2.

Regarding claim 101, Gottesman discloses an umbrella shape as set forth in figure 2.

Claim 103 is rejected under 35 U.S.C. 102(b) as being anticipated by Holloway et al. (5,381,562).

As to claim 103, Holloway discloses a medical basin for collecting fluid during irrigation of a wound on a human anatomy comprising at least one sidewall and a bottom, the at least one sidewall and the bottom defining a cavity; and at least one convertible portion in at least one of the bottom and the at least one sidewall, wherein the at least one convertible portion is configured to define an aperture through the at least one sidewall and bottom when the at least one convertible portion is modified as set forth in col. 7, lines 3 – 15 and in figure 1.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 33, 35 – 39 and 43 – 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon et al. (US 6,558,344).

With reference to claim 31, McKinnon et al. (hereinafter “McKinnon”) discloses an irrigation kit comprising: a flexible sheet having an aperture (figures 2 – 3) configured to engage an irrigation device (figure 7); and a basin (72) for collecting

irrigation fluid used during an irrigation procedure as set forth in figure 14.

The difference between McKinnon and claim 31 is the provision that the basin is sterilized and made of a biocompatible hypoallergenic material.

It would have been obvious to one of ordinary skill in the art to sterilize the basin of McKinnon and produce it with a biocompatible hypoallergenic material since the basin of material is used provide safe and effective wound cleansing to remove dirt, gravel, etc. from a wound site (col. 1, lines 12 – 21). It is well known in the art to sterilize such a device in order to provide enhanced infection control (col. 9, lines 14 – 17). Likewise, it would have been obvious to one of ordinary skill in the art to provide the device with biocompatible, hypoallergenic material in order to prevent an undesirable reaction between the patient and the product.

As to claim 33, McKinnon discloses an irrigation kit wherein the aperture, in an enlarged state, is configured to fit over a conical splash shield extending distally from a collar attached to a tip of the irrigation device as set forth in figure 9.

As to claim 35, McKinnon discloses a flexible sheet having a shape selected from the group consisting of a circle, a square, a rectangle, a half-circle, a star and a diamond as set forth in figures 1 – 2.

The difference between McKinnon and claim 36 is the provision that the flexible sheet has a specific thickness.

McKinnon discloses a flexible sheet that would ultimately have a thickness.

It would have been obvious to one of ordinary skill in the art to modify the thickness of McKinnon in order to determine the most effective product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range includes only a level of ordinary skill in the art.

Regarding claim 37, McKinnon discloses an irrigation kit wherein the flexible sheet is configured to have an umbrella shape as set forth in figures 1 – 2.

As to claim 38, McKinnon discloses an irrigation kit wherein the flexible sheet is pleated to define an umbrella shape as set forth in figures 1 and 4.

The difference between McKinnon and claim 39 is the provision that the flexible sheet has a specific length.

McKinnon discloses a flexible sheet that has a length as set forth in col. 2, lines 57 – 62.

It would have been obvious to one of ordinary skill in the art to modify the length of McKinnon in order to determine the most effective product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range includes only a level of ordinary skill in the art.

As to claims 43 – 47, McKinnon discloses an irrigation kit wherein the basin is configured to collect fluid during irrigation of a wound on various body parts as set forth in col. 8, lines 51 – 61.

With reference to claim 48, McKinnon discloses an irrigation kit further comprising a grommet (44) as set forth in figure 1.

Claims 31 – 32, 34 and 49 – 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greco (US 5,312,385).

With reference to claim 31, Greco discloses an irrigation kit comprising: a flexible sheet having an aperture (4) configured to engage an irrigation device (5); and a basin (6) for collecting irrigation fluid used during an irrigation procedure as set forth in figure 1.

The difference between Greco and claim 31 is the provision that the basin is sterilized and made of a biocompatible hypoallergenic material.

It would have been obvious to one of ordinary skill in the art to sterilize the basin of Greco and produce it with a biocompatible hypoallergenic material since the basin of material because it is well known in the art to sterilize such a device in order to provide enhanced infection control. Likewise, it would have been obvious to one of ordinary skill in the art to provide the device with biocompatible, hypoallergenic material in order to prevent an undesirable reaction between the patient and the product.

With reference to claim 32, Greco teaches a cannula having an adhesive surface as set forth in col. 4, lines 49 – 55.

Regarding claim 34, Greco teaches a flexible sheet that is made from at least one material selected from the group consisting of polyurethane, polypropylene, polyvinyl chloride, and polyvinyl acetate as set forth in col. 4, lines 27 – 31.

As to claims 49 and 50, Greco teaches an irrigation kit wherein the basin has at least one surface, said surface having at least one convertible portion in the form of a frangible portion as set forth in col. 4, lines 62 – 64.

Claims 40 – 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon et al. (US 6,558,344) and further in view of Gottesman et al. (US 4,834,068).

The difference between McKinnon and claim 40 is the provision that an elastic member is attached around the aperture.

Gottesman teaches an irrigation shield comprising a flexible sheet having an elastically enlargeable aperture configured to releasably engage a head of an irrigation nozzle as set forth in col. 4, lines 4 – 17.

It would have been obvious to one of ordinary skill in the art to modify the aperture of McKinnon to provide elastic because the elastic will allow for a tensioned diameter that will provide a convenient leak tight seal as taught by Gottesman in col. 4, lines 6 – 11.

As to claims 41 and 42, Gottesman teaches an irrigation shield wherein the elastic member comprises a latex portion having an elastically enlargeable and/or deformable opening as set forth in col. 4, lines 6 – 11 and in figure 2.

Claim 102 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gottesman et al. (US 4,834,068).

Gottesman discloses a flexible sheet that has a length as set forth in figure 2.

It would have been obvious to one of ordinary skill in the art to modify the length of Gottesman in order to determine the most effective product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range includes only a level of ordinary skill in the art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 571-272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Michele Kidwell  
Primary Examiner  
Art Unit 3761